Complete Summary

GUIDELINE TITLE

Induction of labour.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Women's and Children's Health. Induction of labour. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jul. 32 p. (Clinical guideline; no. 70).

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Royal College of Obstetricians and Gynaecologists. Induction of labour. London: RCOG Press; 2001 Jun. 78 p. (Evidence-based clinical guidelines; no. 9). [158 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Conditions for which induction of labor may be indicated, including:

- Prolonged pregnancy
- Preterm prelabor rupture of membranes
- Prelabor rupture of membranes
- Presence of fetal growth restriction
- Previous caesarean section
- History of precipitate labor
- Maternal request for labor induction
- Breech presentation

- Intrauterine fetal death
- Suspected macrosomia

GUIDELINE CATEGORY

Counseling Evaluation Management Prevention Risk Assessment

CLINICAL SPECIALTY

Anesthesiology
Family Practice
Internal Medicine
Nursing
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Health Care Providers Nurses Patients Physician Assistants Physicians Public Health Departments

GUIDELINE OBJECTIVE(S)

- To review all aspects of the methodology of induction of labour and the appropriateness of different approaches in the various clinical circumstances that may call for such an intervention
- To provide guidance on the:
 - Clinical indications for induction of labour
 - Appropriate place and timing of induction of labour
 - Care that should be offered to women during the induction process, including when to consider fetal and maternal monitoring, analgesia and emotional support; this includes providing information for pregnant women (and their partners/families)
 - Effectiveness of methods used for cervical priming; this includes intracervical and intravaginal prostaglandins
 - Effectiveness of methods used for induction of labour; this includes membrane sweeping, drugs (such as prostaglandins and oxytocin) and amniotomy; the guideline considers all relevant methods and routes of administration
 - Management offered if the cervix is unfavourable
 - Management of complications of induction, such as failed induction

TARGET POPULATION

Women in England and Wales who may need to undergo induction of labor

Note: The following groups that are not covered in this guideline:

- Women with diabetes
- Women with multifetal pregnancy
- Women undergoing augmentation (rather than induction) of labor

INTERVENTIONS AND PRACTICES CONSIDERED

Management

- 1. Patient education
- 2. Obtaining informed consent
- 3. Risk assessment
- 4. Induction of labour
 - Membrane sweeping
 - Vaginal prostaglandin E₂ (PGE₂)
 - Misoprostol or mifepristone only in cases of intrauterine fetal death
 - Methods not recommended for induction of labour
- 5. Setting and timing of labour
- 6. Monitoring of induction
- 7. Pain relief
- 8. Prevention and management of complications, including uterine hyperstimulation, failed induction, cord prolapse, uterine rupture

MAJOR OUTCOMES CONSIDERED

- Rate of vaginal births not achieved within 24 hours
- Uterine hyperstimulation with fetal heart rate (FHR) changes
- Operative delivery rates: caesarean birth
- Serious neonatal morbidity or perinatal death (seizures, birth asphyxia defined by triallists, neonatal encephalopathy, disability in childhood)
- Serious maternal morbidity or death (uterine rupture, admission to intensive care unit, septicaemia)
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Women's and Children's Health

(NCC-WCH) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Literature Search Strategy

Initial scoping searches were executed to identify relevant guidelines (local, national and international) produced by other development groups. The reference lists in these guidelines were checked against subsequent searches to identify missing evidence.

Relevant published evidence to inform the guideline development process and answer the clinical questions was identified by systematic search strategies. Additionally, stakeholder organizations were invited to submit evidence for consideration by the Guideline Development Group (GDG) provided that it was relevant to the clinical questions and of equivalent or better quality than evidence identified by the search strategies.

Systematic searches to answer the clinical questions formulated and agreed by the GDG were executed using the following databases via the OVID platform: Medline (1966 onwards), Embase (1980 onwards), Cumulative Index to Nursing and Allied Health Literature (1982 onwards), PsycINFO (1967 onwards), Cochrane Central Register of Controlled Trials (1st quarter 2007), Cochrane Database of Systematic Reviews (1st quarter 2007), and Database of Abstracts of Reviews of Effects (1st quarter 2007).

Search strategies combined relevant controlled vocabulary and natural language in an effort to balance sensitivity and specificity. Unless advised by the GDG, searches were not date specific. Language restrictions were not applied to searches. Both generic and specially developed methodological search filters were used appropriately.

Searches to identify economic studies were undertaken using the above databases and the National Health Service (NHS) Economic Evaluations Database (NHS EED) produced by the Centre for Reviews and Dissemination at the University of York.

There was no systematic attempt to search grey literature (conferences, abstracts, theses and unpublished trials). Hand searching of journals not indexed on the databases was not undertaken.

At the end of the guideline development process, searches were re-run, thereby including evidence published and included in the databases up to 9 October 2007. Any evidence published after this date was not included. This date should be considered the starting point for searching for new evidence for future updates to this guideline.

The search strategies, including the methodological filters employed, are available on the CD-ROM that accompanies the full guideline (see the "Availability of Companion Documents" field).

NUMBER OF SOURCE DOCUMENTS

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for Intervention Studies

Level	Source of Evidence
1++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High-quality systematic reviews of case-control or cohort studies; high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3	Non-analytical studies (for example, case reports, case series)
4	Expert opinion, formal consensus

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

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Synthesis of Clinical Effectiveness Evidence

Evidence relating to clinical effectiveness was reviewed using established guides and classified using the established hierarchical system shown in the "Rating

Scheme for the Strength of the Evidence." This system reflects the susceptibility to bias that is inherent in particular study designs.

The type of clinical question dictates the highest level of evidence that may be sought. In assessing the quality of the evidence, each study receives a quality rating coded as '++', '+' or '-'. For issues of therapy or treatment, the highest possible evidence level (EL) is a well-conducted systematic review or meta-analysis of randomised controlled trials (RCTs; EL = 1++) or an individual RCT (EL = 1+). Studies of poor quality are rated as '-'. Usually, studies rated as '-' should not be used as a basis for making a recommendation, but they can be used to inform recommendations.

For each clinical question, the highest available level of evidence was selected. Where appropriate, for example, if a systematic review, meta-analysis or RCT existed in relation to a question, studies of a weaker design were not included. Where systematic reviews, meta-analyses and RCTs did not exist, other appropriate experimental or observational studies were sought.

For economic evaluations, no standard system of grading the quality of evidence exists. Economic evaluations that are included in the review have been assessed using a quality assessment checklist based on good practice in decision-analytic modelling.

Evidence was synthesised qualitatively by summarising the content of identified papers in a narrative manner with brief statements accurately reflecting the evidence and by producing evidence tables. Quantitative synthesis (meta-analysis) was performed where appropriate.

Summary results and data are presented in the guideline text. More detailed results and data are presented in the evidence tables are available on the CD-ROM that accompanies the full guideline (see the "Availability of Companion Documents" field). Where possible, dichotomous outcomes are presented as relative risks (RRs) with 95% confidence intervals (CIs), and continuous outcomes are presented as mean differences with 95% CIs or standard deviations (SDs). Meta-analyses based on dichotomous outcomes are presented as pooled odds ratios (ORs) with 95% CIs, and meta-analyses based on continuous outcomes are presented as weighted mean differences (WMDs) with 95% CIs.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)
Expert Consensus (Nominal Group Technique)
Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

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(NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Who Has Developed the Guideline?

The guideline was developed by a multi-professional and lay working group (the Guideline Development Group or GDG) convened by the NCC-WCH. Membership included:

- Two obstetricians/gynaecologists
- Two specialists in fetal and maternal medicine
- One neonatologist
- Three midwives
- Three women's representatives
- One external adviser

Staff from the NCC-WCH provided methodological support for the guideline development process, undertook systematic searches, retrieval and appraisal of the evidence and health economics modelling and wrote successive drafts of the guideline.

Interpretation of the Evidence and Formulation of Recommendations

The evidence tables and narrative summaries for the clinical questions being reviewed were made available to the GDG members for their perusal 1 week before the scheduled GDG meeting. For each clinical question, recommendations for clinical care were derived using, and linked explicitly to, the evidence that supported them. In the first instance, informal consensus methods were used by the GDG to agree clinical and cost-effectiveness evidence statements. Statements summarising the GDG's interpretation of the evidence and any extrapolation from the evidence used to form recommendations were also prepared. The process by which the evidence statements informed the recommendations is summarised in the 'Interpretation of evidence' section. In areas where no substantial research evidence was identified, the GDG considered other evidence-based guidelines and consensus statements or used their collective clinical experience to form recommendations, based on current best practice. Where evidence was limited or lacking to answer particular clinical questions, the GDG formulated recommendations for future research.

Shortly before the consultation period, formal consensus methods were used to agree on guideline recommendations, using a modified Delphi method, and to select five key recommendations considered as priorities for implementation, using a nominal group technique.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Health Economics

The aim of the economic input into the guideline was to inform the Guideline Development Group (GDG) of potential economic issues relating to induction of labour. The health economist helped the GDG by identifying topics within the guideline that might benefit from economic analysis, reviewing the available economic evidence and, where necessary, conducting (or commissioning) economic analysis. Reviews of published health economic evidence are presented alongside the reviews of clinical evidence and are incorporated within the relevant evidence statement and recommendations. For some questions, no published evidence was identified, and decision-analytic modelling was undertaken.

Economic evaluations in the guideline have been conducted in the form of a cost-effectiveness analysis, with the health effects measured in an appropriate non-monetary outcome indicator. The National Institute for Health and Clinical Excellence (NICE) technology appraisal programme measures outcomes in terms of quality-adjusted life years (QALYs). Where possible, this approach has been used in the development of this guideline. However, where it has not been possible to estimate QALYs gained as a result of an intervention, an alternative measure of effectiveness has been used.

Cost-effectiveness analysis, with the units of effectiveness expressed in QALYs (known as cost-quality of life analysis) is widely recognised as a useful approach for measuring and comparing the efficiency of different health interventions. The QALY is a measure of health outcome which assigns to each period of time (generally 1 year) a weight, ranging from 0 to 1, corresponding to health-related quality of life during that period. It is one of the most commonly used outcome measures in health economics. A score of 1 corresponds to full health and a score of 0 corresponds to a health state equivalent to death. Negative valuations, implying a health state worse than death, are possible. Health outcomes using this method are measured by the number of years of life in a given health state multiplied by the value of being in that health state.

The key economic question addressed in this guideline is 'what is the cost-effective date during pregnancy to first offer the woman the choice of induction of labour?'. The model compares different strategies for offering pharmaceutical induction based on the number of completed weeks and days of pregnancy. Details of this modelling are presented in Appendix D in the full version of the original guideline document.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This guideline has been developed in accordance with the National Institute for Health and Clinical Excellence (NICE) guideline development process. This has included giving registered stakeholder organisations the opportunity to comment on the scope of the guideline at the initial stage of development and on the evidence and recommendations at the concluding stage. The developers have carefully considered and responded to all of the comments during these two stages. The Guideline Developers Group (GDG)'s responses to the stakeholders'

comments were reviewed independently by the Guideline Review Panel convened by NICE.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Women's and Children's Health (NCC-WCH) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Information and Decision-making

This section should be read in conjunction with 'Antenatal care: routine care for the healthy pregnant woman' (see the NGC summary of the NICE clinical guideline Antenatal care: Routine care for the healthy pregnant woman), and 'Intrapartum care: care of healthy women and their babies during childbirth' (NICE clinical guideline 55), available from www.nice.org.uk/CG055.

Women should be informed that most women will go into labour spontaneously by 42 weeks. At the 38 week antenatal visit, all women should be offered information about the risks associated with pregnancies that last longer than 42 weeks, and their options. The information should cover:

- Membrane sweeping:
 - That membrane sweeping makes spontaneous labour more likely, and so reduces the need for formal induction of labour to prevent prolonged pregnancy
 - What a membrane sweep is
 - That discomfort and vaginal bleeding are possible from the procedure
- Induction of labour between 41⁺⁰ and 42⁺⁰ weeks
- Expectant management

Healthcare professionals should explain the following points to women being offered induction of labour:

- The reasons for induction being offered
- When, where and how induction could be carried out
- The arrangements for support and pain relief (recognising that women are likely to find induced labour more painful than spontaneous labour) (see also the first two recommendations under "Pain Relief" below)
- The alternative options if the woman chooses not to have induction of labour
- The risks and benefits of induction of labour in specific circumstances and the proposed induction methods
- That induction may not be successful and what the woman's options would be.

Healthcare professionals offering induction of labour should:

- Allow the woman time to discuss the information with her partner before coming to a decision
- Encourage the woman to look at a variety of sources of information
- Invite the woman to ask questions and encourage her to think about her options
- Support the woman in whatever decision she makes

Induction of Labour in Specific Circumstances

Prevention of Prolonged Pregnancy

Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour.

Women with uncomplicated pregnancies should usually be offered induction of labour between 41^{+0} and 42^{+0} weeks to avoid the risks of prolonged pregnancy. The exact timing should take into account the woman's preferences and local circumstances.

If a woman chooses not to have induction of labour, her decision should be respected. Healthcare professionals should discuss the woman's care with her from then on.

From 42 weeks, women who decline induction of labour should be offered increased antenatal monitoring consisting of at least twice-weekly cardiotocography and ultrasound estimation of maximum amniotic pool depth. (This recommendation is from 'Antenatal care: routine care for the healthy pregnant woman', see the NGC summary of the NICE guideline Antenatal care: Routine care for the healthy pregnant woman).

Preterm Prelabour Rupture of Membranes

If a woman has preterm prelabour rupture of membranes, induction of labour should not be carried out before 34 weeks unless there are additional obstetric indications (for example, infection or fetal compromise).

If a woman has preterm prelabour rupture of membranes after 34 weeks, the maternity team should discuss the following factors with her before a decision is made about whether to induce labour, using vaginal prostaglandin E₂ (PGE₂*):

- Risks to the woman (for example, sepsis, possible need for caesarean section)
- Risks to the baby (for example, sepsis, problems relating to preterm birth)
- Local availability of neonatal intensive care facilities

*Vaginal PGE_2 has been used in UK practice for many years in women with ruptured membranes. However, the summary of product characteristics (SPCs) (July 2008) advise that in this situation, vaginal PGE_2 is either not recommended or should be used with caution, depending on the preparation (gel, tablet or pessary). Healthcare professionals should refer to the individual SPCs before prescribing vaginal PGE_2 for women with ruptured membranes, and informed consent should be obtained and documented.

Prelabour Rupture of Membranes at Term

Women with prelabour rupture of membranes at term (at or over 37 weeks) should be offered a choice of induction of labour with vaginal PGE_2^* or expectant management.

*Vaginal PGE_2 has been used in UK practice for many years in women with ruptured membranes. However, the summary of product characteristics (SPCs) (July 2008) advise that in this situation, vaginal PGE_2 is either not recommended or should be used with caution, depending on the preparation (gel, tablet or pessary). Healthcare professionals should refer to the individual SPCs before prescribing vaginal PGE_2 for women with ruptured membranes, and informed consent should be obtained and documented.

Induction of labour is appropriate approximately 24 hours after prelabour rupture of the membranes at term. (This recommendation is from 'Intrapartum care: care of healthy women and their babies during childbirth' (NICE clinical guideline 55). Available from http://guidance.nice.org.uk/CG55.

Previous Caesarean Section

If delivery is indicated, women who have had a previous caesarean section may be offered induction of labour with vaginal PGE₂**, caesarean section or expectant management on an individual basis, taking into account the woman's circumstances and wishes. Women should be informed of the following risks with induction of labour:

- Increased risk of need for emergency caesarean section during induced labour
- Increased risk of uterine rupture

** Vaginal PGE_2 has been used in UK practice for many years in women with a history of previous caesarean section. However, the SPCs (July 2008) advise that the use of vaginal PGE_2 is not recommended in women with a history of previous caesarean section. Informed consent on the use of vaginal PGE_2 in this situation should therefore be obtained and documented.

Maternal Request

Induction of labour should not routinely be offered on maternal request alone. However, under exceptional circumstances (for example, if the woman's partner is soon to be posted abroad with the armed forces), induction may be considered at or after 40 weeks.

Breech Presentation

Induction of labour is not generally recommended if a woman's baby is in the breech presentation. If external cephalic version is unsuccessful, declined or contraindicated, and the woman chooses not to have an elective caesarean section, induction of labour should be offered, if delivery is indicated, after discussing the associated risks with the woman.

Fetal Growth Restriction

If there is severe fetal growth restriction with confirmed fetal compromise, induction of labour is not recommended.

History of Precipitate Labour

Induction of labour to avoid a birth unattended by healthcare professionals should not be routinely offered to women with a history of precipitate labour.

Intrauterine Fetal Death

In the event of an intrauterine fetal death, healthcare professionals should offer support to help women and their partners and/or family cope with the emotional and physical consequences of the death. This should include offering information about specialist support.

In the event of an intrauterine fetal death, if the woman appears to be physically well, her membranes are intact and there is no evidence of infection or bleeding, she should be offered a choice of immediate induction of labour or expectant management.

In the event of an intrauterine fetal death, if there is evidence of ruptured membranes, infection or bleeding, immediate induction of labour is the preferred management option.

If a woman who has had an intrauterine fetal death chooses to proceed with induction of labour, oral mifepristone, followed by vaginal PGE₂ or vaginal misoprostol***, should be offered. The choice and dose of vaginal prostaglandin should take into account the clinical circumstances, availability of preparations and local protocol.

***At the time of publication (July 2008), misoprostol was not licensed for use for labour induction in fetal death in utero in the UK. Informed consent should therefore be obtained and documented.

For women who have intrauterine fetal death and who have had a previous caesarean section, the risk of uterine rupture is increased. The dose of vaginal prostaglandin** should be reduced accordingly, particularly in the third trimester.

** Vaginal PGE_2 has been used in UK practice for many years in women with a history of previous caesarean section. However, the SPCs (July 2008) advise that the use of vaginal PGE_2 is not recommended in women with a history of previous caesarean section. Informed consent on the use of vaginal PGE_2 in this situation should therefore be obtained and documented.

Suspected Fetal Macrosomia

In the absence of any other indications, induction of labour should not be carried out simply because a healthcare professional suspects a baby is large for gestational age (macrosomic).

Recommended Methods for Induction of Labour

Membrane sweeping involves the examining finger passing through the cervix to rotate against the wall of the uterus, to separate the chorionic membrane from the decidua. If the cervix will not admit a finger, massaging around the cervix in the vaginal fornices may achieve a similar effect. For the purpose of this guideline, membrane sweeping is regarded as an adjunct to induction of labour rather than an actual method of induction.

The Bishop score is a group of measurements made by doing a vaginal examination, and is based on the station, dilation, effacement (or length), position and consistency of the cervix. A score of eight or more generally indicates that the cervix is ripe, or 'favourable' – when there is a high chance of spontaneous labour, or response to interventions made to induce labour.

Membrane Sweeping

Prior to formal induction of labour, women should be offered a vaginal examination for membrane sweeping.

At the 40 and 41 week antenatal visits, nulliparous women should be offered a vaginal examination for membrane sweeping. (This recommendation is from <u>Antenatal care: routine care for the healthy pregnant woman</u>. See the NGC summary of the NICE clinical guideline).

At the 41 week antenatal visit, parous women should be offered a vaginal examination for membrane sweeping.

When a vaginal examination is carried out to assess the cervix, the opportunity should be taken to offer the woman a membrane sweep.

Additional membrane sweeping may be offered if labour does not start spontaneously.

Pharmacological Methods

Vaginal PGE_2 is the preferred method of induction of labour, unless there are specific clinical reasons for not using it (in particular the risk of uterine hyperstimulation). It should be administered as a gel, tablet or controlled-release pessary. Costs may vary over time, and trusts/units should take this into consideration when prescribing PGE_2 . For doses, refer to the SPCs. The recommended regimens are:

- One cycle of vaginal PGE₂ tablets or gel: one dose, followed by a second dose after 6 hours if labour is not established (up to a maximum of two doses)
- One cycle of vaginal PGE₂ controlled-release pessary: one dose over 24 hours

When offering PGE₂ for induction of labour, healthcare professionals should inform women about the associated risks of uterine hyperstimulation.

Misoprostol* should only be offered as a method of induction of labour to women who have intrauterine fetal death (see the section " Intrauterine Fetal Death" above) or in the context of a clinical trial.

*At the time of publication (July 2008), misoprostol was not licensed for use for labour induction in fetal death in utero in the UK. Informed consent should therefore be obtained and documented.

Mifepristone should only be offered as a method of induction of labour to women who have intrauterine fetal death (see the section "Intrauterine Fetal Death" above).

Methods That Are Not Recommended for Induction of Labour

Pharmacological Methods

The following should not be used for induction of labour:

- Oral PGE₂
- Intravenous PGE₂
- Extra-amniotic PGE₂
- Intracervical PGE₂
- Intravenous oxytocin alone
- Hyaluronidase
- Corticosteroids
- Oestrogen
- Vaginal nitric oxide donors

Non-pharmacological Methods

Healthcare professionals should inform women that the available evidence does not support the following methods for induction of labour:

- Herbal supplements
- Acupuncture
- Homeopathy
- Castor oil
- Hot baths
- Enemas
- Sexual intercourse

Surgical Methods

Amniotomy, alone or with oxytocin, should not be used as a primary method of induction of labour unless there are specific clinical reasons for not using vaginal PGE₂, in particular the risk of uterine hyperstimulation.

Mechanical Methods

Mechanical procedures (balloon catheters and laminaria tents) should not be used routinely for induction of labour.

Setting and Timing

In the outpatient setting, induction of labour should only be carried out if safety and support procedures are in place.

The practice of induction of labour in an outpatient setting should be audited continuously.

In the inpatient setting, induction of labour using vaginal PGE₂ should be carried out in the morning because of higher maternal satisfaction.

Monitoring and Pain Relief

Monitoring

Wherever induction of labour is carried out, facilities should be available for continuous electronic fetal heart rate and uterine contraction monitoring.

Before induction of labour is carried out, Bishop score should be assessed and recorded, and a normal fetal heart rate pattern should be confirmed using electronic fetal monitoring.

After administration of vaginal PGE_2 , when contractions begin, fetal wellbeing should be assessed with continuous electronic fetal monitoring. Once the cardiotocogram is confirmed as normal, intermittent auscultation should be used unless there are clear indications for continuous electronic fetal monitoring as described in 'Intrapartum care' (NICE clinical guideline 55).

If the fetal heart rate is abnormal after administration of vaginal PGE2, recommendations on management of fetal compromise in 'Intrapartum care' (NICE clinical guideline 55) should be followed.

Bishop score should be reassessed 6 hours after vaginal PGE_2 tablet or gel insertion, or 24 hours after vaginal PGE_2 controlled-release pessary insertion, to monitor progress (see the first recommendation under "Pharmacological Methods" in "Recommended Methods for Induction of Labour" above).

If a woman returns home after insertion of vaginal PGE₂ tablet or gel, she should be asked to contact her obstetrician/midwife:

- When contractions begin
- If she has had no contractions after 6 hours

Once active labour is established, maternal and fetal monitoring should be carried out as described in 'Intrapartum care' (NICE clinical guideline 55).

Pain Relief

Women being offered induction of labour should be informed that induced labour is likely to be more painful than spontaneous labour.

Women should be informed of the availability of pain relief options in different settings (see the second recommendation under "Information and Decision-Making" and the first recommendation under "Setting and Timing" above).

During induction of labour, healthcare professionals should provide women with the pain relief appropriate for them and their pain (as described in 'Intrapartum care' [NICE clinical guideline 55]). This can range from simple analgesics to epidural analgesia. Birth attendants (carers and healthcare professionals) should offer women support and analgesia as required, and should encourage women to use their own coping strategies for pain relief.

The opportunity to labour in water is recommended for pain relief. (This recommendation is from 'Intrapartum care: care of healthy women and their babies during childbirth' (NICE clinical guideline 55). Available from http://guidance.nice.org.uk/CG55.)

Prevention and Management of Complications

Uterine Hyperstimulation

Tocolysis should be considered if uterine hyperstimulation occurs during induction of labour.

Failed Induction

Failed induction is defined as labour not starting after one cycle of treatment as described in the first recommendation under "Pharmacological Methods" in "Recommended Methods for Induction of Labour" above.

If induction fails, healthcare professionals should discuss this with the woman and provide support. The woman's condition and the pregnancy in general should be fully reassessed, and fetal wellbeing should be assessed using electronic fetal monitoring.

If induction fails, decisions about further management should be made in accordance with the woman's wishes, and should take into account the clinical circumstances.

If induction fails, the subsequent management options include:

- A further attempt to induce labour (the timing should depend on the clinical situation and the woman's wishes)
- Caesarean section (refer to the NGC summary of the NICE clinical guideline <u>Caesarean section</u>.)

For women who choose caesarean section after a failed induction, recommendations in <u>Caesarean section</u> (see the NGC summary of the NICE clinical quideline) should be followed.

Cord Prolapse

To reduce the likelihood of cord prolapse, which may occur at the time of amniotomy, the following precautions should be taken:

- Before induction, engagement of the presenting part should be assessed.
- Obstetricians and midwives should palpate for umbilical cord presentation during the preliminary vaginal examination and avoid dislodging the baby's head.

Amniotomy should be avoided if the baby's head is high.

Healthcare professionals should always check that there are no signs of a low-lying placental site before membrane sweeping and before induction of labour.

Uterine Rupture

If uterine rupture is suspected during induced labour, the baby should be delivered by emergency caesarean section (refer to the NGC summary of the NICE clinical guideline <u>Caesarean section</u>).

CLINICAL ALGORITHM(S)

The original guideline document provides a care pathway for induction of labour.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of the guideline may decrease complications and improve outcomes for women and their babies in women who undergo induction of labour.

POTENTIAL HARMS

- More pain during childbirth
- Requirement for instrumental intervention or caesarean section
- Greater strain on labour wards

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer and informed by the summary of product characteristics of any drugs they are considering.

- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.
- The guideline assumes that prescribers will use a drug's summary of product characteristics (SPC) to inform their decisions for individual women.
- The use of registered names, trademarks, etc. in this publication does not imply, even in the absence of a specific statement, that such names are exempt from the relevant laws and regulations and therefore for general use.
- While every effort has been made to ensure the accuracy of the information contained within this publication, the publisher can give no guarantee for information about drug dosage and application thereof contained in this book. In every individual case the respective user must check current indications and accuracy by consulting other pharmaceutical literature and following the guidelines laid down by the manufacturers of specific products and the relevant authorities in the country in which they are practising.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health' (available from www.dh.gov.uk). Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

NICE has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (http://guidance.nice.org.uk/CG70).

- Slides highlighting key messages for local discussion
- A costing statement explaining the resource impact of this guidance
- Audit support for monitoring local practice

Key Priorities for Implementation

Information and Decision-Making

- Women should be informed that most women will go into labour spontaneously by 42 weeks. At the 38 week antenatal visit, all women should be offered information about the risks associated with pregnancies that last longer than 42 weeks, and their options. The information should cover:
 - Membrane sweeping:
 - That membrane sweeping makes spontaneous labour more likely, and so reduces the need for formal induction of labour to prevent prolonged pregnancy

- What a membrane sweep is
- That discomfort and vaginal bleeding are possible from the procedure
- Induction of labour between 41⁺⁰ and 42⁺⁰ weeks
- Expectant management
- Healthcare professionals should explain the following points to women being offered induction of labour:
 - The reasons for induction being offered
 - When, where and how induction could be carried out
 - The arrangements for support and pain relief (recognising that women are likely to find induced labour more painful than spontaneous labour) (see also the recommendations under "Pain Relief" in the "Major Recommendations" section.)
 - The alternative options if the woman chooses not to have induction of labour
 - The risks and benefits of induction of labour in specific circumstances and the proposed induction methods
 - That induction may not be successful and what the woman's options would be

Induction of Labour to Prevent Prolonged Pregnancy

 Women with uncomplicated pregnancies should usually be offered induction of labour between 41⁺⁰ and 42⁺⁰ weeks to avoid the risks of prolonged pregnancy. The exact timing should take into account the woman's preferences and local circumstances.

Preterm Labour Rupture of Membranes

- If a woman has preterm prelabour rupture of membranes after 34 weeks, the maternity team should discuss the following factors with her before a decision is made about whether to induce labour, using vaginal prostaglandin E2 (PGE₂)
 - Risks to the woman (for example, sepsis, possible need for caesarean section)
 - Risks to the baby (for example, sepsis, problems relating to preterm birth)
 - Local availability of neonatal intensive care facilities

Vaginal PGE₂

- Vaginal PGE₂ is the preferred method of induction of labour, unless there are specific clinical reasons for not using it (in particular the risk of uterine hyperstimulation). It should be administered as a gel, tablet or controlled-release pessary. Costs may vary over time, and trusts/units should take this into consideration when prescribing PGE₂. For doses, refer to the summary of product characteristics (SPCs). The recommended regimens are:
 - One cycle of vaginal PGE₂ tablets or gel: one dose, followed by a second dose after 6 hours if labour is not established (up to a maximum of two doses)
 - One cycle of vaginal PGE₂ controlled-release pessary: one dose over 24 hours

Failed Induction

- If induction fails, healthcare professionals should discuss this with the woman and provide support. The woman's condition and the pregnancy in general should be fully reassessed, and fetal wellbeing should be assessed using electronic fetal monitoring.
- If induction fails, the subsequent management options include:
 - A further attempt to induce labour (the timing should depend on the clinical situation and the woman's wishes)
 - Caesarean section (refer to the NGC summary of the NICE clinical guideline <u>Caesarean section</u>).

IMPLEMENTATION TOOLS

Audit Criteria/Indicators Clinical Algorithm Patient Resources Quick Reference Guides/Physician Guides Resources Slide Presentation

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Women's and Children's Health. Induction of labour. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jul. 32 p. (Clinical guideline; no. 70).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jun (revised 2008 Jul)

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Women's and Children's Health - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence

GUIDELINE COMMITTEE

Guideline Development Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All Guideline Development Group members' interests were recorded on a declaration form provided by the National Institute for Health and Clinical Excellence (NICE) and are listed in Appendix A of the full version of the original guideline document. The form covered consultancies, fee-paid work, shareholdings, fellowships and support from the healthcare industry.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Royal College of Obstetricians and Gynaecologists. Induction of labour. London: RCOG Press; 2001 Jun. 78 p. (Evidence-based clinical guidelines; no. 9). [158 references]

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>National Institute</u> for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Induction of labour. Full guideline. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Jul. 124 p. (Clinical guideline; no. 70). Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Induction of labour. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence; 2008 Jul. 10 p. (Clinical guideline; no. 70). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Induction of labour. Costing report. Implementing NICE guidance. London (UK): National Institute for Health and Clinical Excellence; 2008 Jul. 3 p. (Clinical guideline; no. 70). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Induction of labour. Audit support. London (UK): National Institute for Health and Clinical Excellence; 2008 Oct. 12 p. (Clinical guideline; no. 70). Electronic copies: Available in Portable Document Format (PDF) from the <u>NICE Web site</u>.
- Induction of labour. Slide set. London (UK): National Institute for Health and Clinical Excellence; 2008. 15 p. (Clinical guideline; no. 70). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- The guidelines manual 2007. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 April. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1625. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

Induction of labour. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence; 2008 Jul. 8 p. (Clinical guideline; no. 70). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1626. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the

authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on November 26, 2001. The information was verified by the guideline developer as of February 22, 2002. This summary was updated by ECRI Institute on September 30, 2009.

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Date Modified: 1/4/2010

